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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/923,629      | 08/07/2001  | Gerhard Wollmann     | C 2272 COGG         | 2062             |

23657 7590 01/10/2003

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| EXAMINER |
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BADIO, BARBARA P

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1616

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/923,629

Applicant(s)

WOLLMANN ET AL.

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**First Office Action on the Merits**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3 and 6-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al. ('252) and Hunt ('669) in combination.

Hunt et al. ('252) teach a process for the recovery of tocopherols from a starting material containing fatty and sterol compounds, such as distillates of vegetable oils and fats (see the entire article, especially col. 4, lines 23-58). The reference teaches (a) esterifying the free fatty acids preferably with a lower alcohol; (b) transesterifying the fatty acid glyceride esters present by mixing said tocopherol mixture with a lower alcohol in the presence of a zinc catalyst; (c) removal of the excess lower alcohol, zinc catalyst, fatty acid alkyl ester and glycerol and (d) for complete conversion of sterol esters in the tocopherol mixture to free sterols, reacting said tocopherol mixture obtained with a lower alcohol in the presence of an alkoxide catalyst in order to produce a tocopherol mixture containing free sterols and fatty acid alkyl esters (see col. 3, line 47 – col. 4, line 67). The reference teaches the transesterification of sterol esters is preferably conducted at a temperature between about 150°C and about 240°C and in

reaction times of 10 minutes or more, such as 1 to about 3 hours under pressure (see col. 6, lines 24-44).

Hunt ('669) teaches a similar process for the recovery of tocopherols from a mixture comprising of fatty acids, sterols and tocopherols (see the entire article, especially col. 2, line 66 – col. 3, line 62). The reference teaches (a) esterification of the free fatty acids present in the mixture with lower or higher alcohols (see col. 3, lines 19-22 and col. 4, lines 1-5); (b) transterifying fatty acid esters present in the mixture with a lower alcohol in the presence of a basic catalyst such as potassium hydroxide and sodium methoxide (see col. 3, lines 23-25 and col. 9, lines 9-28) and (c) removal of excess lower alcohol, basic catalyst, fatty acid alkyl ester and glycerol (see col. 3, lines 26-35 and col. 6, line 67 – col. 7, line 13).

Based on the combined teachings of the above cited references, the recovery of sterols from starting materials containing fatty and sterol compounds such as vegetable oils by a process comprising the removal of the free fatty acids by esterification; transesterification of the fatty acid glyceride esters in the presence of a lower alcohol and basic catalyst; removal of the excess alcohol, basic catalyst, fatty acid alkyl ester and glycerol; and conversion of the sterol esters in the product obtained by transesterification would be obvious to the skilled artisan in the art at the time of the invention.

The instant claims differ by reciting the transesterification of the sterol esters is at a temperature of from 115°C to 145°C and a pressure of from 2 to 10 bar for a period of from 3 to 10 hours. However (a) Hunt et al. ('252) teach said transesterification can be

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done at temperatures between **about** 150°C and about 240°C and in reaction times of 10 minutes or more, such as **1 to about 3 hours** under pressure and (b) optimization of the reaction by variation in reaction conditions such as, temperature, pressure and/or reaction time is with the level of skill of the ordinary artisan. The motivation to make changes to the reaction conditions would be based on the desire to obtain optimum conditions resulting in increase yield of the desired product. Thus, the claimed process would have been obvious based on prior art teachings and the level of skill of ordinary artisan in the art at the time of the invention.

The limitations recited in claim 31 are noted. However, as stated in the present specification, said follow-up processes for concentration sterols are known in the art (see page 9, paragraph 0038). Thus, concentration of said sterols as recited by the instant claim would be obvious to the skilled artisan in the art at the time of the invention.

3. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunt et al. ('252) and Hunt ('669) in combination as applied to claim 1 above, and further in view of Hernandez et al. ('423).

Claims 4 and 5 further differ by reciting the removal of free fatty acids by neutralization utilizing sodium metasilicate, precipitation and separation. However, Hernandez et al. ('423) teach silicate solutions, for example sodium metasilicate, are useful in removal of free fatty acid in crude oils such as crude vegetable oils (see the entire article, especially col. 3, lines 45-58). Therefore, the removal of free fatty acid by

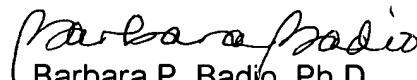
the use of sodium metasilicate would have been obvious to the skilled artisan at the time of the instant invention. The motivation to modify the process taught by Hunt ('252 and '669) by removing the free fatty acid by neutralization with a silicate solution such as sodium metasilicate is based on the teachings of Hernandez that said is a non-caustic means for removal of impurities from vegetable oils and a desire to obtain alternate means of removal of free fatty acids from mixtures such as vegetable oils.

### ***Telephone Inquiry***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Barbara P. Badio, Ph.D.  
Primary Examiner  
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